Rexall Sundown

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September 17, 1998

RECEIVED 9/22/98

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Rexall Sundown, Inc. located at 851 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 within the past thirty days marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Cernitin AF: [It] offers men a safe and effective nutritional approach to prostate health through multiple mechanisms of action: by supporting smooth muscle function surrounding the urinary tract; and by promoting prostate function for healthy urinary flow. Cernitin AF, a unique combination of Cernitin, standardized Beta Sitosterol and Saw Palmetto, is designed to provide nutritional support for prostate and urinary health. The ingredients in Cernitin AF help support smooth muscle tissue function. Cernitin AF supports healthy prostate and urinary function.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Corporate Counsel

Enclosure

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